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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,687	01/29/2004	Robert G. Ulrich	Army140D	8007

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U.S. Army Medical Research
and Materiel Command
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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,687	ULRICH ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *100-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-99 have been cancelled. Claims 100-102 were newly added in the preliminary amendment filed 1/29/04. Claims 103-114 have been newly added in the amendment filed 9/14/06. Claims 100-114 are under consideration by the examiner.

Specification

The disclosure is objected to because of the following informalities: The specification fails to reference or identify the SEQ ID NOS. disclosed in the sequence listing in the brief description of the drawings (see for example description of Figure 3 on page 10).

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. Correction of the following is required: The recombinant DNA construct pETB2360210 (see claim 100) does not appear to be disclosed in the specification. Note that this is not a new matter rejection as the originally filed claims recite these constructs. The specification must be amended to refer to the claimed subject matter. Applicant is directed to 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification at pages 21-22 and 32 do not name these constructs.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data

sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

Applicant is requested to insert reference to parent application 08/882,431 as set forth above.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The

Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 100 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 10 of prior U.S. Patent No. 6,713,284 B2. Both claims are directed to the same pETB2360210 DNA construct. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 101-114 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,713,284 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because overlapping embodiments of SEB superantigen toxin DNA fragments, constructs, host cells, and methods of production.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 101-114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant application is a divisional application of 08/882,431, now U.S. Patent 6,713,284 B2. Claims 101-102 are not originally filed claims and were newly added in the preliminary amendment filed 1/29/04. Claims 103-114 have been newly added in the amendment filed 9/14/06. No specific basis was pointed to for any of these claims and none is apparent. Claim 1 of the '284 patent recites "at least one amino acid selected from the group consisting of amino acid positions 40-50, 62-72, 84-94 and 110-120 of SEB, and at least one amino acid of amino acid positions 18-28, 55-65, 86-96, 89-99, and 205-215 of SEB." This differs conceptually from instant claim 101 which recites "at least one amino acid of amino acid positions 40-50 of SEB and at least one amino acid selected from the group consisting of amino acid positions 18-28, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215 of SEB." The concept of combining mutations in this way to result in the recited properties is not seen in the specification. Applicant is requested to point to particular basis for claims 101-114.

Claim 100 and 104-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The enablement of claims 37-39 requires availability of the named DNA constructs and a deposit should have been made in accordance with MPEP 2402. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited materials will be made irrevocably available with no restrictions upon issuance of a patent. No such statement has been provided nor does the specification appear to reflect the deposit information (ATCC numbers, date of deposit, address of the depository, etc.).

It is noted that applicant perfected this deposit in parent application 08/882,431; however, no documentation concerning the deposit has been submitted in the instant application. No corresponding amendments to the specification concerning the deposit have been made in the instant application.

Claims 104-106 are directed to host cells and methods of producing altered superantigen toxins using the host cells. Because the claims do not indicate that these are isolated host cells the claims can be construed to encompass transgenic animals and methods of producing the toxins in transgenic animals. Such animals and methods do not appear to be disclosed nor enabled by the specification. It would not have been routine to produce toxins in this manner at the time of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 102, 107-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 107 recites "wherein the at least one amino acid includes amino acid positions 18-28." It is unclear whether all of these positions must be mutated or only at least one from this set. Claims 102 and 108-114 are similarly confusing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 101, 103-104, and 106 are rejected under 35 U.S.C. 102(a) as being anticated by Bavari et al. (Vaccines 96).

The authorship of the reference is Bavari, Olson, Dyas, and Ulrich. The inventorship opf the instant application is Ulrich, Olson, and Bavari. As such, this reference is by other within the meaning of 102(a) and valid prior art.

Bavari et al. disclose mutating the Staphylococcal enterotoxin B (SEB) in the hydrophobic loop, polar pocket, and disulfide loop to disrupt MHC class-II binding. (See figures

3-4 and page 138, refined vaccine structure.) Although not explicitly disclosed, production of these engineered vaccines would have required the claimed DNA fragments, expression vectors, host cells, and methods of production. The reference clearly relies upon standard site-directed mutagenesis and recombinant production techniques that would have been well known to one of ordinary skill in the art at the time of the invention. The instant specification makes clear on pages 19-20 that the hydrophobic loop corresponds to positions 40-50 and the polar pocket corresponds to positions 62-72, 84-94, and 110-120. As such, the reference is deemed to anticipate the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hayball et al. (International Immunology, 1994) discloses the recombinant production of SEB in which positions 60 and 61 have been mutated and result in altered T cell receptor binding. SEB Y61A appears to possess the properties recited in claim 101. See abstract, methods at page 200, and Table 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen
Primary Examiner
Art Unit 1647

9/22/2006

mpa